Complete Summary

GUIDELINE TITLE

Obtaining consent for chemotherapy.

BIBLIOGRAPHIC SOURCE(S)

Treleaven J, Cullis JO, Maynard R, Bishop E, Ainsworth-Smith I, Roques A, Webb A, Favre J, Milligan D, British Committee for Standards in Haematology. Obtaining consent for chemotherapy. Br J Haematol 2006 Mar;132(5):552-9. [5 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cancer and other diseases requiring chemotherapy

GUIDELINE CATEGORY

Counseling
Management

CLINICAL SPECIALTY

Hematology
Internal Medicine
Oncology

INTENDED USERS

Nurses
Physicians

GUIDELINE OBJECTIVE(S)

To set out guidelines specifically addressing the issues which surround obtaining consent for the administration of chemotherapy in the haemato-oncology setting

Note: Most of the points considered are of relevance in all the other areas involving patient treatment where consent must be sought.

TARGET POPULATION

Patients in the United Kingdom who require chemotherapy to treat their disease

INTERVENTIONS AND PRACTICES CONSIDERED

1. Oral versus written consent
2. Documentation of consent or refusal
3. Withdrawal of consent
4. Consent process in emergencies
5. Obtaining consent in special cases:
    - Impaired capacity
    - Visual or auditory impairment
    - Illiteracy
    - Minors
    - Patients whose first language is not English
6. Patient access to health professionals
7. Responsibility for consent
8. Consent training

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

General Issues Relating to Consent

Patients have a fundamental legal and ethical right to determine what happens to their own bodies and parts of them. Obtaining valid consent from patients who are to undergo treatment in the haemato-oncology setting is therefore absolutely essential, as it is in all other aspects of healthcare, from the relatively simple, such as providing personal care, to the more complex situations, such as

undergoing a surgical procedure. Seeking consent is also a matter of common courtesy between health professionals and patients, and the process of obtaining consent should constitute a forum for ensuring that a patient is fully acquainted with all aspects of his/her treatment, in the immediate, intermediate and late situations. The basic requirements of consent may be summarised as follows:

1. Agreement without coercion.
2. Agreement based on information given – see later 'Provision of information.'
3. The ability to understand the proposal and come to a rational decision.

Guidance on Consent

The Department of Health Reference guide to consent for examination or treatment provides a comprehensive summary of the current law on consent, and includes the requirements of regulatory bodies such as the General Medical Council where these are more stringent. These guidelines should be consulted for details of the law and good practice requirements on consent. They may be accessed on the internet and incorporate both the law and good practice advice for:

1. Health professionals working with children, where only those with 'parental responsibility' are entitled to give consent on behalf of their children.
2. For those working with people with learning disabilities and those lacking the capacity to give or withhold consent.
3. For those working with older people.

In addition to the above-mentioned guidelines, '12 key points on consent: the law in England' has been distributed widely to health professionals working in England. This is a one-page document, which summarises those aspects of the law on consent which arise on a daily basis. It is attached as Appendix A in the original guideline document, and copies are also available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006131.

General Issues About Obtaining Consent for Chemotherapy

All health professionals involved with the administration of chemotherapy should be aware of any guidance on consent issued by their own regulatory bodies and those put in place by their hospital trust.

Informed consent should always be obtained from the patient for:

- Oral chemotherapy
- Intravenous chemotherapy, both bolus and infusional
- Intrathecal chemotherapy
- Chemotherapy given into the pleura or peritoneum
- Chemotherapy prior to a stem cell transplant procedure

Documenting Consent

It is essential for health professionals to document clearly both a patient's agreement to the intervention, and the discussions which led up to that agreement. This may be performed either through the use of a consent form, with further detail in the patient's notes, or through documenting in the patient's notes that they have given oral consent. Written consent should only be seen by healthcare professionals as good practice and as documentation of the discussion, rather than as a means of assuring an effective legal defence if their actions are later challenged in court. Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is evidence that the patient has given consent, but is not proof of valid consent. If a patient is hurried into signing a form having been given too little information or without having had the opportunity to discuss the information given, the consent may not be valid, despite the signature. In law, a patient wholly ignorant of that to which he appends a signature of consent is not, in reality, consenting at all. Such a signature may be evidence of a relationship of trust, but not evidence of a comprehension of what is intended. Also, if a patient has given valid verbal consent, the fact that he/she is physically unable to sign the form is no bar to treatment, and patients may withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract. *It is important to be aware, therefore that written consent has little, if any more, legal force than does oral consent. Informed verbal consent is quite valid and should not be regarded as 'second best.'*

However consent is obtained, written information should be provided concerning every chemotherapy protocol being used. This should contain detailed information, written in layman's terms, about:

a. Treatment intention
b. Expected response rates
c. Anticipated side effects including incidence of morbidity and mortality from neutropenia
d. Duration of treatment – numbers of cycles of chemotherapy and length of time in hospital for each course
e. Possible late effects of chemotherapy including sterility, second malignancies
f. Necessity for blood product transfusion, administration of antibiotics and antifungal agents

Specific Issues Concerning Chemotherapy Consent

Nature of the Consent Form

If it is planned to give several courses of drugs over a period of weeks or months and if a consent form is to be used, it is acceptable to have one consent form expressing that a specific number of courses of chemotherapy are to be given. Alternatively, one consent form may be used for all courses, with the dates of each course entered at the bottom, and the patient can initial these before each course commences. The latter ensures that paperwork is kept to the minimum while at the same time providing a further record of dates and duration of chemotherapy administered.

Reconsidering Treatment/Withdrawing Consent

There should always be the opportunity for the patient to reconsider treatment options in the light of response or lack of response. He/she should also be in the position to withdraw or modify consent at any point if the treatment is perceived by either the patient or his carer to be ineffective in terms of disease control, or if the patient is unable to tolerate therapy because of toxicities and/or side effects. Such a change in consent should embrace both stopping chemotherapy entirely, modifying doses in an attempt to reduce toxicity, or changing to a different regimen entirely. Any changes in treatment should be carefully documented in the patient's notes.

Provision of Information

This may be improved by the use of video recordings or compact discs, which the patient can take home and assimilate in the relatively unstressed environment of his/her own surroundings. Many centres now also record or videotape individual consent/information sessions. This provides the patient with an accurate record of what has been said in his/her particular case.

Before patients can come to a decision about treatment, they need understandable information about their condition and possible treatment options. Investigations require explanation, as do risks and benefits, including the option of doing nothing. Information sheets can be produced for each individual protocol along with a description of the patient's haematological disorder. In all of these situations, the possible side-effects should be included even if they are rare, although care should be taken to emphasise the unlikely nature of any rare events so as not to alarm the patient unduly. Most trusts produce a series of booklets and leaflets about cancer, its treatment, effects and side effects, and listing the support sources available to people living with cancer. Patients also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, and about what will happen after treatment – what to do in the event of a problem, how long they will be in hospital, how they will feel afterwards.

Use of Flow Charts and Diagrams

The provision of a 'flow chart' should be considered, so that patients can obtain a clear concept of duration of their proposed chemotherapy protocol and can also see when a particular intervention, such as a bone marrow test or lumbar puncture, is likely to be undertaken. Care should be taken to explain that such a flow chart is only a guideline, however, and that it may be necessary to delay or change the time of a particular intervention, for example in the light of a low blood count.

Quantity of Information Provided

Patients and their family vary in how much information they want. Some require as much detail as possible, including information about rare risks, whereas some ask health professionals to make decisions for them and do not wish to be informed of possible side-effects and complications of proposed therapy. This is known as 'competent refusal to be informed.' There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks

and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented. It should not be seen as grounds for denying the existence of valid consent, although it clearly calls into question the concept of 'informed consent' being an absolute requirement before treatment can begin. That the offer to provide details has been made and refused should be recorded.

Stages in the Consent Process

The consent process should have at least two stages, the first being the provision of information, discussion of options and initial (oral) decision, and the second being confirmation that the patient still wants to go ahead. In most cases where written consent is being sought, treatment options will have been discussed well in advance of the actual procedure being carried out. This may be on just one occasion, or it might be over a whole series of consultations with a number of different health professionals. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

Documentation of Decision Making

Patients should be given a copy of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure. A member of the healthcare team must check with the patient whether they have any further concerns if there is a significant delay between the patient consenting to treatment and that treatment being instigated. When confirming consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with 'tell me what you're expecting to happen,' rather than 'is everything all right?'

Refusal of Treatment

The patient must always feel that it would have been possible for them to refuse, or change their mind for consent to be valid. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983. The situation for children is more complex and is explained in the Department of Health Guidelines. If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in the notes. If the patient has already signed a consent form, but then changes their mind, this should also be documented in the notes by the health care professional and, where possible, the patient. The patient should also be made aware that he is free to change his/her mind and accept treatment later if he wishes to do so. Where delay may influence a treatment choice, the patient should be advised accordingly.

The situation with respect to refusal of consent to medical treatment, both generally and where there is impaired capacity, is given in Appendix B of the original guideline document as a set of guidelines which were issued by Butler Sloss through the Court of Appeal in St George's Healthcare NHS Trust v S (1998).

Other Issues Relating to Consent

The Consent Process in an Emergency Situation

In urgent cases, it may be necessary to initiate chemotherapy, or other support measures, such as antibiotic therapy or blood product support, immediately after discussing the situation with the patient. However, if the therapy proposed carries significant risks, as with the treatment of acute myeloid leukaemia for example, health professionals must take into consideration whether the patient has had sufficient opportunity to absorb the information necessary to make a decision. The most appropriate approach in such a setting is to have a written consent form available for the patient to read through, which contains:

- A summary of likely immediate and delayed side effects of the intended chemotherapy regimen
- Aims in terms of anticipated cure-rate
- Time to be spent in hospital
- How many courses of chemotherapy the patient can expect

Such an approach will give the patient a background of information, upon which he/she can base any future questions that may arise as the treatment progresses. In the complex situation of haemato-oncology any newly diagnosed patient must, by necessity, assimilate a great deal of information while feeling unwell and having to adapt to the new environment of the hospital. Consent should thus be viewed as a 'longitudinal' process, with the patient being able to withdraw consent at any time if he/she decides not to proceed with treatment, once the immediate danger is over.

Obtaining Consent Where There Is Impaired Capacity

As mentioned above, under 'Refusal of Treatment,' the Court of Appeal in England and Wales has issued guidelines relating to consent where there is a question of capacity, which are summarised above and set out in full in Appendix B of the original guideline document. In law, capacity is

- The ability to understand information that is relevant to the decision about treatment.
- The ability to believe in that information.
- The ability to weigh it in the balance when arriving at a choice.

Incompetence may be temporary, perhaps induced by confusion, pain or drugs, fluctuating or permanent. If a patient has a fluctuating ability to retain information, assistance should be provided to help the patient reach an informed decision while competent, and this decision should be reviewed before the treatment starts, to confirm that the patient's views are consistent. All discussions should be documented.

In English law there is no provision for proxy consent in the case of a permanently incompetent patient. No one is entitled to give consent on his/her behalf. However, it would clearly not be acceptable for such a patient to be denied appropriate treatment just because he/she is unable to consent for him/ herself, and in such circumstances the doctor is expected to treat the patient in accordance with his 'best interests', as judged by a responsible body of medical opinion.

In Scotland, the situation regarding the medical treatment of patients with impaired capacity is defined by statute, the Adults with Incapacity Act (Scotland) 2000 Part 5. Further information on this legislation can be found at http://www.scotland-legislation.hmso.gov.uk/legislation/scotland/acts2000/20000004.htm.

In some cases a formal assessment of capacity conducted by a mental health professional may be necessary.

Obtaining Consent From a Patient with Special Needs

Care should be taken to ensure that patients with special needs, such as those who have visual or auditory impairment or who are illiterate, receive information regarding their situation in a manner most likely to ensure that they are able to comprehend what is intended. Such information may be delivered entirely verbally or entirely visually, depending on the requirements of the patient.

Obtaining Consent From Minors

The Family Law Reform Act 1969 gives competent minors in England and Wales between the ages of 16 and 18 years the ability to consent to medical treatment. It was not until 1986, however, that the situation with regard to younger children was considered in the case of Gillick v West Norfolk Area Health Authority (1985). It is now accepted that as long as a younger child is capable of understanding what is proposed, and of expressing his/her own wishes, a minor should be regarded as having the capacity to consent to medical intervention. The doctor may encourage the child to allow parental involvement, but if such involvement is refused the confidentiality of the competent minor should be respected unless there are strong reasons not to do so, for example, when child protection issues arise.

In Scotland the law concurs with that of England although the concept of 'Gillick' competency does not exist in law. The rights of a minor as regards to consent to medical treatment in Scotland are defined by statute in the Age of Legal Capacity (Scotland) Act (1991).

Minors who are under the age of 18 years who are Gillick competent but who refuse treatment present a more difficult dilemma: it is always prudent to seek a declaration from the Court before proceeding with treatment which is perceived to be in their best interests.

Provision for Patients Whose First Language Is Not English

Patients whose first language is not English should receive the information they need and be enabled to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members who do not speak English. Neither is it appropriate to use another patient, or the relatives of that patient, to interpret. Many trusts may have a contractual arrangement with 'Language Line', a translating service which is offered by telephone. Alternatively, an in-house interpreting service may be available.

Where an interpreter, or family member providing interpretation is used to provide consent information, this should be documented on the consent form and/or in the patient notes. Where the interpreter is present they should be requested to read and sign the appropriate section of the consent form. When using 'Language Line' the member of staff should request the translator's identification number, which should be documented on the consent form, along with the time and location of the conversation to enable cross referencing with invoices.

Access to Health Professionals Between Formal Appointments

After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions, which they would like to answer before they make their decision. Information regarding contact numbers of appropriate health professionals, such as specialist nurses, should be provided as part of the initial discussions.

Responsibility for Seeking Consent

The healthcare professional carrying out the procedure is ultimately responsible for ensuring that the patient is giving valid consent, and it is they who will be held responsible in law if this is challenged later. However, team-work is now the way the National Health Service operates and, where written consent is being sought, it may be appropriate for several members of the team to participate in the process of seeking consent. It is the responsibility of the healthcare professional to ensure that when he/she requires a colleague to seek consent on his/her behalf he/she is confident that the colleague will work within his/her own competence and will not agree to perform tasks which exceed that competence.

Completing Consent Forms

As outlined above, it is now perceived by both patients and healthcare professionals that it is desirable to have an 'extended' consent form available for patients which contains more information about the intended procedure beyond whether they agree to the treatment or not.

If the patient signs the form in advance of the procedure, a health professional involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered. It is appropriate for any member of the healthcare team (for e.g. a nurse admitting the patient for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer questions they cannot handle themselves. This should be clearly recorded in the patient's notes, along with an outline of the conversation which had taken place.

Consent Training

Many trusts now run consent training sessions, targeted at all new medical and clinical staff who may have patient contact. Such training should cover:

- The process for seeking consent in the trust

- The legality of the consent seeking process – where and when
- How to communicate the risks and benefits
- The process for confirming consent

Health professionals involved in confirming consent should have access to the patient's consultant and/or medical team. In working hours there should always be one member of the patient's medical team on site to answer any remaining questions that a patient may have. Out of hours, the health professional should have access to the senior nurse on duty, the Senior House Officer and Specialist Registrar on call. The patient's consultant should also be contactable.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Patient understanding of and consent to necessary chemotherapy procedures
- Legal protection for the patient and the health provider

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

While the advice and information in this guideline document is believed to be true and accurate at the time of going to press, neither the authors, the British Society for Haematology nor the publishers accept any legal responsibility for the content of these guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Getting Better
Living with Illness

IOM DOMAIN

Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Treleaven J, Cullis JO, Maynard R, Bishop E, Ainsworth-Smith I, Roques A, Webb A, Favre J, Milligan D, British Committee for Standards in Haematology. Obtaining consent for chemotherapy. Br J Haematol 2006 Mar;132(5):552-9. [5 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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2006 Mar

GUIDELINE DEVELOPER(S)

British Committee for Standards in Haematology - Professional Association

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GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the British Committee for Standards in Haematology Web site.

Print copies: Available from the British Committee for Standards in Haematology; Email: bcsh@b-s-h.org.uk.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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